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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,941	08/24/2001	Robin Thurmond	ORT-1489	2660

7590 03/25/2004

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,941	THURMOND ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/4/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-4 are pending and are under examination.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it has been signed by inventors but not dated.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step a) lacks antecedent basis in reciting, "the subject treated".

Claim 1, step b) is vague and indefinite in lacking a correlation step. Specifically, it is unclear how the step of "measuring the accumulation of an intermediate degradation of invariant chain (Ii) in the blood sample" correlates to the "effect of in vivo administration of cathepsin S inhibitor" in the preamble.

Claims 2-4 have improper antecedent basis problems in reciting, "A method according to claim".

Claim 2, step a) is indefinite in being redundant with step a) of claim 1.

Claim 2 is confusing because it is unclear where steps a) to d) is performed in relation to steps a) and b) in claim 1 from which it depends.

Claim 3 is indefinite in reciting, "ELISA". Acronyms and abbreviations should be recited at least one time in a given set of claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. (WO 99/58153) in view of Willman et al. (US Patent 6,495,333).

Chapman et al. disclose monitoring the effect of in vivo administration of cathepsin S inhibitor in a subject (see Abstract and page 14, lines 7-29). Chapman et al. specifically teach that by detecting the presence of invariant chain on surface of a cell, i.e. dendritic cell or antigen presenting cell, using labeled Ii-specific antibody, the effect of in vivo cathepsin S inhibitor to inhibit cathepsin S activity can be monitored (see page 3, line 32 to page 4, line 4 and lines 14-18, and page 13, lines 16-23). Anti-Ii chain antibodies are used diagnostically in ELISA to evaluate Ii chain expression in vivo (see page 9). Cathepsin S inhibitors include antisense cathepsin nucleic acid molecules and cathepsin inhibitory molecules which are peptides based on vinylsulfone (see page 2, lines 1-10). In practice, Chapman et al. show the effects of cathepsin S inhibitors to Ii degradation by obtaining a cell sample of splenocytes, lysing the cells, then analyzing the lysates for the presence or accumulation of intermediate degradation product of Ii having a 10 kDa fragment, i.e. p10Ii fragment (see Example III, especially, page 17, lines 6-15).

Chapman et al. differ from the instant invention in failing to disclose using blood sample taken from a subject to measure the presence of intermediate degradation product of Ii.

Willman et al. disclose that dendritic cells or antigen presenting cells [from which invariant chains are contained] are present in peripheral blood samples for use in analytical assays (see Abstract and column 5, lines 7-47).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to detect the presence of intermediate degradation product of Ii, i.e. p10Ii, as taught by Chapman, using peripheral blood samples taught in the method of Willman, because Willman recognized the difficulty in studying function in dendritic cells because of their rarity, but showed that ease in collection of blood as opposed to lymphatic tissue, achieves the goal of non-invasive procedures in monitoring compound activity for pharmaceutical evaluation studies of autoimmune disorders such as in the method of Chapman.

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 18, 2004

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641